Docket No. 21281/0208272-US0
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Amit Krishna Antarkar, *et al.*

Application No.: 10/518,044 Confirmation No.: 2710

Filed: August 17, 2005 Art Unit: 1618

For: PROCESS OF MANUFACTURE OF NOVEL DRUG DELIVERY SYSTEM: MULTILAYER TABLET COMPOSITION OF THIAZOLIDINEDIONE AND BIGUANIDES

Examiner: YOUNG, MICAH PAUL

INTERVIEW SUMMARY

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Paper summarizes the Interview conducted with Examiner Young on June 22, 2010.

Remarks begin on page 2 of this paper.

Applicants believe that no fees are necessary with this submission. Should any additional fees be necessary in connection with this submission, the Commissioner is hereby authorized and requested to charge Deposit Account No. 02-2555 for any such fees.

REMARKS

Applicants thank Examiner Young for his time in conducting a telephone Interview with Applicant's representative, Dr. Jonathan P. Mitchell, on June 22, 2010.

During the Interview, Examiner Young and Dr. Mitchell discussed International Publication No. WO 00/28989 ("Lewis"), in particular, Example 4b of Lewis. Dr. Mitchell pointed out to the Examiner that Layer B of the tri-layer tablet in Example 4b of Lewis does not contain 345 mg Eudragit RS powder, as contended by the Examiner in the June 1, 2010 Advisory Action.

The term "Eudragit RS powder to 345" recited in Example 4b refers to the amount of Eudragit RS powder required to bring the total weight of Layer B of the tablet up to 345 mg after the weight of all the other components in Layer B are taken into account. In other words, the amount of Eudragit RS powder is equal to the difference between (1) 345 mg and (2) the total amount of metformin hydrochloride (250 mg) and Eudragit L100-55 (74 mg).

In Example 4b, the amount of Eudragit RS powder in Layer B is, therefore, 21 mg/tablet (i.e., 345 – (250 + 74) mg).

Thus, in Example 4b, the total amount of Eudragit L100-55 and Eudragit RS present in metformin hydrochloride containing layers (Layers B and C) is 95 mg per tablet (i.e., 74 + 21 mg). The total amount of metformin hydrochloride in Layers B and C is 500 mg. Accordingly, the amount of non-biodegradable polymer in the metformin hydrochloride containing layers of Example 4b is 19 % by weight of the metformin hydrochloride (i.e., 95 * 100/500). This is a significantly lower content than in the biguanide-containing layer(s) of the multilayer dosage form of the presently claimed invention.

Even if, for the sake of completeness, one were to consider the polyvinyl pyrrolidone present in Layer C (7.5 mg) to be a non-biodegradable inert polymer, the total amount of non-biodegradable polymer in the metformin hydrochloride containing layers of Example 4b would be 20.5 % by weight of the metformin hydrochloride (i.e., (95 + 7.5) * 100/500). Again, this is a significantly lower content than in the biguanide-containing layer(s) of the multilayer dosage form of the presently claimed invention.

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Therefore, Lewis does not disclose or suggest a dosage form for pH independent release of a biguanide and immediate release of thiazolidinedione, in which the biguanide layers include a non-biodegradable inert polymer in an amount of at least 35% by weight of biguanide in the dosage form, as recited in the pending claims.

Dated: June 29, 2010

Respectfully submitted,

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